SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Metered Dose Inhaler Formula-
tion

Version 1.16  Revision Date: 09.04.2021  SDS Number: 25999-00017  Date of last issue: 16.10.2020
Date of first issue: 28.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Mometasone Metered Dose Inhaler Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A
Telephone: 551-430-6000
E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Aerosols, Category 3 H229: Pressurised container: May burst if heated.
Long-term (chronic) aquatic hazard, Cat-
egory 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms:

Signal word: Warning

Hazard statements:
H229 Pressurised container: May burst if heated.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251 Do not pierce or burn, even after use.
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P273  Avoid release to the environment.
Response:
P391  Collect spillage.
Storage:
P410 + P412  Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.

Additional Labelling
Contains fluorinated greenhouse gases. (HFC-227ea)
2.5 % by mass of the contents are flammable.

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

May displace oxygen and cause rapid suffocation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration ( % w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>603-002-00-5</td>
<td></td>
<td>Flam. Liq. 2; H225</td>
<td>&gt;= 1,8 - &lt;= 2,5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>specific concentration limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319 &gt; 50 %</td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 1B; H360Df STOT RE 2; H373</td>
<td>&gt;= 0,08 - &lt;= 0,18</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410</td>
<td></td>
</tr>
</tbody>
</table>
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</thead>
</table>

#: Voluntarily-disclosed non-hazardous substance  
For explanation of abbreviations see section 16.  

SECTION 4: First aid measures  

4.1 Description of first aid measures  

General advice  
In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.  

Protection of first-aiders  
First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  

If inhaled  
If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention immediately.  

In case of skin contact  
In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.  

In case of eye contact  
Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.  

If swallowed  
If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  

4.2 Most important symptoms and effects, both acute and delayed  

Risks  
Gas reduces oxygen available for breathing.  

4.3 Indication of any immediate medical attention and special treatment needed  

Treatment  
Treat symptomatically and supportively.
SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.
- If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.

Hazardous combustion products:
- Carbon oxides
- Fluorine compounds

5.3 Advice for firefighters

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Evacuate personnel to safe areas.
- Ventilate the area.
- Use personal protective equipment.
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spillages cannot be contained.
6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep tightly closed. Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Do not pierce or burn, even after use. Keep cool. Protect from sunlight.

Advice on common storage:
- Do not store with the following product types:
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Oxidizing agents
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Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures, which in contact with water, emit
flammable gases
Explosives
Gases

7.3 Specific end use(s)
Specific use(s) : No data available

No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>Ethanol</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>114 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
</tr>
<tr>
<td>1,1,1,2,3,3,3-Heptafluoropropane</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>61279 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6533 mg/m³</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Fresh water</td>
<td>0,96 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>2,75 mg/l</td>
</tr>
</tbody>
</table>

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Marine water  0.79 mg/l
Sewage treatment plant  580 mg/l
Fresh water sediment  3.6 mg/kg dry weight (d.w.)
Marine sediment  2.9 mg/kg dry weight (d.w.)
Soil  0.63 mg/kg dry weight (d.w.)
Oral (Secondary Poisoning)  380 mg/kg food
1,1,1,2,3,3,3-Heptafluoropropane Fresh water  0.1 mg/l
Intermittent use/release  1 mg/l
Sewage treatment plant  1.73 mg/l
Fresh water sediment  1.3 mg/kg

8.2 Exposure controls

Personal protective equipment
Skin and body protection: Skin should be washed after contact.
Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 137

Filter type: Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: Aerosol containing a dissolved gas
Colour: white to off-white
Odour: odourless
Odour Threshold: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: -16 °C
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
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SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: If the temperature rises there is danger of the vessels bursting due to the high vapor pressure. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

Ethanol:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
- Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
  Exposure time: 4 h
  Test atmosphere: vapour

Mometasone:
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
- LD50 (Mouse): > 2,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 3.3 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Remarks: No mortality observed at this dose.
  LC50 (Mouse): > 3.2 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- Acute toxicity (other routes of administration): LD50 (Rat): 300 mg/kg
  Application Route: Subcutaneous
  Symptoms: Breathing difficulties

Skin corrosion/irritation
Not classified based on available information.

Components:

Ethanol:
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
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**Mometasone:**
- **Species:** Rabbit
- **Result:** No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Ethanol:**
- **Species:** Rabbit
- **Method:** OECD Test Guideline 405
- **Result:** Irritation to eyes, reversing within 21 days

**Mometasone:**
- **Species:** Rabbit
- **Result:** No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Ethanol:**
- **Test Type:** Local lymph node assay (LLNA)
- **Exposure routes:** Skin contact
- **Species:** Mouse
- **Result:** negative

**Mometasone:**
- **Test Type:** Maximisation Test
- **Exposure routes:** Dermal
- **Species:** Guinea pig
- **Assessment:** Does not cause skin sensitisation.
- **Result:** negative
- **Remarks:** The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Ethanol:**
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Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

Genotoxicity in vivo:
- Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  Species: Mouse
  Application Route: Ingestion
  Result: equivocal

Mometasone:
- Genotoxicity in vitro:
  Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: Chromosomal aberration
  Test system: Chinese hamster lung cells
  Result: negative
  Test Type: Chromosomal aberration
  Test system: Chinese hamster ovary cells
  Result: positive
  Test Type: Mouse Lymphoma
  Result: negative

- Genotoxicity in vivo:
  Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative
  Test Type: Chromosomal aberration
  Species: Rat
  Cell type: Bone marrow
  Result: negative
  Test Type: unscheduled DNA synthesis assay
  Species: Rat
  Cell type: Liver cells
  Result: negative

Germ cell mutagenicity- Assessment:
Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Components:
- Mometasone:
  Species: Rat
  Application Route: Inhalation
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</table>

Exposure time: 2 Years
Dose: 0.067 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Inhalation
Exposure time: 19 Months
Dose: 0.160 mg/kg body weight
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

Ethanol:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Mometasone:
Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0.015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced foetal weight
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
Result: Embryotoxic effects, Teratogenicity and development-
toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight
Result: Effects on newborn

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 0,7 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments. Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure
Not classified based on available information.

Components:
Mometasone:
Remarks: Based on available data, the classification criteria are not met.

STOT - repeated exposure
Not classified based on available information.

Components:
Mometasone:

Repeated dose toxicity

Components:
Ethanol:
Species: Rat
NOAEL: 1.280 mg/kg
LOAEL: 3.156 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Mometasone:
Species: Rat
NOAEL: 0,005 mg/kg
LOAEL: 0,3 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
Species: Dog  
LOAEL: 0.5 mg/kg  
Application Route: Oral  
Exposure time: 30 d  
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Rat  
NOAEL: 0.00013 mg/l  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 90 d  
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species: Dog  
NOAEL: 0.0005 mg/l  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 90 d  
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

Aspiration toxicity  
Not classified based on available information.

Components:  
Mometasone: Not applicable

11.2 Information on other hazards

Endocrine disrupting properties

Product:  
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:  
Mometasone:  
Inhalation: Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion

Skin contact: Symptoms: Dermatitis, Itching
Further information

Components:

Mometasone:
Remarks: Dermal absorption possible

SECTION 12: Ecological information

12.1 Toxicity

Components:

Ethanol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 1.000 mg/l
   Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l
   Exposure time: 48 h

Toxicity to algae/aquatic plants:
   ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
      Exposure time: 72 h
   EC10 (Chlorella vulgaris (Fresh water algae)): 11,5 mg/l
      Exposure time: 72 h

Toxicity to microorganisms: EC50 (Pseudomonas putida): 6.500 mg/l
   Exposure time: 16 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
   NOEC: 9,6 mg/l
      Exposure time: 9 d
   Species: Daphnia magna (Water flea)

Mometasone:
Toxicity to fish: LC50 (Menidia beryllina (Silverside)): 0,11 mg/l
   Exposure time: 96 h
   Remarks: No toxicity at the limit of solubility
   LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
   Exposure time: 7 d
   Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:
   EC50 (Daphnia magna (Water flea)): > 5 mg/l
      Exposure time: 48 h
      Method: OECD Test Guideline 202
      Remarks: No toxicity at the limit of solubility
   EC50 (Americamysis): > 5 mg/l
      Exposure time: 96 h
      Method: US-EPA OPPTS 850.1035
      Remarks: No toxicity at the limit of solubility
## Toxicity to algae/aquatic plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

## Toxicity to microorganisms

EC50: > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC: 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

## Toxicity to fish (Chronic toxicity)

NOEC: 0.00014 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

## Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 0.34 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

## M-Factor (Chronic aquatic toxicity)

100

### 12.2 Persistence and degradability

#### Components:

**Ethanol:**

Biodegradability

- Result: Readily biodegradable.
- Biodegradation: 84 %
- Exposure time: 20 d

**Mometasone:**

Biodegradability

- Result: Not readily biodegradable.
- Biodegradation: 50 %
- Exposure time: 28 d
- Method: OECD Test Guideline 314

Stability in water

- Hydrolysis: 50 % (12 d)
- Method: OECD Test Guideline 111
12.3 Bioaccumulative potential

**Components:**

**Ethanol:**
Partition coefficient: n-octanol/water : log Pow: -0.35

**Mometasone:**
Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107.1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4.68

12.4 Mobility in soil

**Components:**

**Mometasone:**
Distribution among environmental compartments : log Koc: 4.02

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**
Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Global warming potential

Regulation (EU) No 517/2014 on fluorinated greenhouse gases

**Product:**
100-year global warming potential: 3.159

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**SECTION 13: Disposal considerations**

13.1 Waste treatment methods

**Product:**
Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes
Contaminated packaging:

- Empty containers should be taken to an approved waste handling site for recycling or disposal.
- If not otherwise specified: Dispose of as unused product.
- Please ensure aerosol cans are sprayed completely empty (including propellant)

### SECTION 14: Transport information

#### 14.1 UN number or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 1950</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 1950</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1950</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 1950</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1950</td>
</tr>
</tbody>
</table>

#### 14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>AEROSOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>AEROSOLS</td>
</tr>
<tr>
<td>RID</td>
<td>AEROSOLS</td>
</tr>
<tr>
<td>IMDG</td>
<td>AEROSOLS (Mometasone)</td>
</tr>
<tr>
<td>IATA</td>
<td>Aerosols, non-flammable</td>
</tr>
</tbody>
</table>

#### 14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
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</thead>
<tbody>
<tr>
<td>ADR</td>
<td>2</td>
</tr>
<tr>
<td>RID</td>
<td>2</td>
</tr>
<tr>
<td>IMDG</td>
<td>2.2</td>
</tr>
<tr>
<td>IATA</td>
<td>2.2</td>
</tr>
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</table>

#### 14.4 Packing group

<table>
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<tr>
<th>ADN</th>
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<tbody>
<tr>
<td>Packing group: Not assigned by regulation</td>
</tr>
<tr>
<td>Classification Code: 5A</td>
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<tr>
<td>Labels: 2.2</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group: Not assigned by regulation</td>
</tr>
<tr>
<td>Classification Code: 5A</td>
</tr>
<tr>
<td>Labels: 2.2</td>
</tr>
<tr>
<td>Tunnel restriction code: (E)</td>
</tr>
</tbody>
</table>
RID
Packing group : Not assigned by regulation
Classification Code : 5A
Hazard Identification Number : 20
Labels : 2.2

IMDG
Packing group : Not assigned by regulation
Labels : 2.2
EmS Code : F-D, S-U

IATA (Cargo)
Packing instruction (cargo aircraft) : 203
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Non-flammable, non-toxic Gas

IATA (Passenger)
Packing instruction (passenger aircraft) : 203
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Non-flammable, non-toxic Gas

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

14.6 Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Maritime transport in bulk according to IMO instruments
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
Mometasone Metered Dose Inhaler Formulation

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Version 1.16
Revision Date: 09.04.2021
SDS Number: 25999-00017
Date of last issue: 16.10.2020
Date of first issue: 28.10.2014

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59), : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

The components of this product are reported in the following inventories:

AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H319 : Causes serious eye irritation.
H360Df : May damage the unborn child. Suspected of damaging fertility.
H373 : May cause damage to organs through prolonged or repeated exposure if inhaled.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit
Mometasone Metered Dose Inhaler Formulation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICGS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:
Aerosol 3  H229
Aquatic Chronic 2  H411

Classification procedure:
Based on product data or assessment
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their...
intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NO / EN